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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/658,884	09/09/2003	Olga Bandman	PF-0179-2 DIV	3217

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EXAMINER	
AEDER, SEAN E	

ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 07/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary	Application No.	Applicant(s)	
	10/658,884	BANDMAN ET AL.	
	Examiner	Art Unit	
	Sean E. Aeder, Ph.D.	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-57 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-57 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

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DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1, 2, 17, 18, and 56, drawn to an isolated polypeptide, classified in class 530, subclass 350.

II. Claims 3-7, 9, 10, 12-13, and 57, drawn to an isolated polynucleotide, classified in class 536, subclass 23.1.

III. Claim 8, drawn to a transgenic organism, classified in class 800, subclass 8.

IV. Claims 11, 31, 32, 34, and 36-43, drawn to an isolated antibody, classified in class 530, subclass 387.1.

V. Claims 14-16, drawn to a method of detecting a target polynucleotide in a sample, classified in class 435, subclass 6.

VI. Claim 19, drawn to a method for treating a disease comprising administering a composition comprising a polypeptide comprising the

amino acid sequence of SEQ ID NO:1, classified in class 424, subclass 184.1.

VII. Claims 20 and 23, drawn to a method of screening a compound for effectiveness as an agonist or an antagonist of a polypeptide comprising the amino acid sequence of SEQ ID NO:1, classified in class 435, subclass 4.

VIII. Claim 21, drawn to a composition comprising an agonist of a polypeptide of SEQ ID NO:1, classified in class 514, subclass 1.

IX. Claim 22, drawn to a method for treating a disease comprising administration to a patient an agonist of a polypeptide of SEQ ID NO:1, classified in class 514, subclass 1.

X. Claim 24, drawn to an antagonist of a polypeptide of SEQ ID NO:1, classified in class 514, subclass 1.

XI. Claim 25, drawn to a method for treating a disease comprising administration to a patient an antagonist of a polypeptide of SEQ ID NO:1, classified in class 514, subclass 1.

XII. Claim 26, drawn to a method of screening for a compound that specifically binds a polypeptide of SEQ ID NO:1, classified in class 435, subclass 7.1.

XIII. Claim 27, drawn to a method of screening for a compound that modulates the activity of a polypeptide of SEQ ID NO:1, classified in class 435, subclass 4.

XIV. Claim 28, drawn to a method for screening for a compound for effectiveness in altering expression of a target polynucleotide of SEQ ID NO:1, classified in class 435, subclass 6.

XV. Claim 29, drawn to a method of screening for potential toxicity of a test compound comprising hybridizing nucleic acids of biological samples with a probe, classified in class 435, subclass 6.

XVI. Claim 30, 33, and 35, drawn to a method to test for a condition or disease associated with the expression of MAGELP, classified in class 435, subclass 7.1.

XVII. Claim 44, drawn to a method of detecting a polypeptide comprising the amino acid sequence of SEQ ID NO:1, classified in class 435, subclass 6.

XVIII. Claim 45, drawn to a method of purifying a polypeptide comprising the amino acid SEQ ID NO:1 from a sample, classified in class 435, subclass 7.1.

XIX. Claims 46 and 48-55, drawn to a microarray, classified in class 435, subclass 810.

XX. Claim 47, drawn to a method of generating an expression profile of a sample which contains polynucleotides, classified in class 435, subclass 810.

The inventions are distinct, each from the other because of the following reasons:

The inventions of groups I-IV, VIII, X, and XIX represent separate and distinct products. Group I is drawn to a polypeptide, group II is drawn to a polynucleotide, group III is drawn to a transgenic organism, group IV is drawn to an antibody, group VIII is drawn to an agonist, group X is drawn to an antagonist, group XIX is drawn to a microarray. These products are made by materially different methods, and are used in materially different methods which have different modes of operation, different functions and different effects. functions and different effects.

The DNA of group II is related to the protein of group I by virtue of the fact that the DNA codes for the protein. The DNA molecule has utility for the recombinant production of the protein in a host cell. Although the DNA and the protein are related, since the DNA encodes the specifically claimed protein, they are distinct inventions because the protein product can be made by other and materially distinct processes, such as purification from the natural source. Further, DNA can be used for processes other than the production of protein, such as nucleic acid hybridization assays.

Furthermore, searching the inventions of groups I and II together would impose a serious search burden. In the instant case, the search of the polypeptides and polynucleotides are not coextensive. The inventions of groups I and II have a separate status in the art as shown by their different classifications. In cases such as this one where descriptive sequence information is provided, the sequences are searched in appropriate database. There is search burden also in the non-patent literature. Prior to the concomitant isolation and expression of the sequences of interest there may be journal articles devoted solely to polypeptides which would not have described the polynucleotide. Similarly, there may have been "classical" genetics papers which had no knowledge of the polypeptide but spoke to the gene. Searching, therefore is not coextensive. A search of the nucleic acid molecules of group II would require an oligonucleotide search, which is not likely to result in relevant art with respect to the polypeptide of group I. As such, it would be burdensome to search the inventions of groups I and II.

The polypeptide of group I and the antibody of group IV are patentably distinct for the following reasons:

While the inventions of both group I and group IV are polypeptides, in this instance the polypeptide of group I represents a purified MAGELP polypeptide, whereas the polypeptide of group I encompasses antibodies including IgG which comprises 2 heavy and 2 light chains containing constant and variable regions, and including framework regions which act as a scaffold for the 6 complementarily determining regions (CDR) that function to bind an epitope. Thus the polypeptide of group I and the antibody of group IV are structurally distinct molecules; any relationship between a polypeptide of group I and an antibody of group IV is dependent upon the correlation between the scope of the polypeptide that the antibody binds and the scope of the antibodies that would be generated upon immunization with the polypeptide. In this case, the polypeptide of group I contains potentially hundreds of regions to which an antibody may bind, whereas the antibody of group IV is defined in terms of its binding specificity to a small structure. Furthermore, searching the inventions of group I and group IV would impose a serious search burden. The inventions have separate status in the art as shown by their different classifications. A polypeptide and an antibody which binds to the polypeptide require different searches. An amino acid sequence search of the full-length protein is necessary for a determination of novelty and unobviousness of the protein. However, such a search is not required to identify the

antibody of group III. Furthermore, antibody which binds to an epitope of a polypeptide of group I may be known even if a polypeptide of group I is novel. In addition, the technical literature search for the polypeptide of group I and the antibody of group IV are not coextensive, e.g., antibodies may be characterized in the technical literature prior to discovery of or sequence of their binding target.

The polynucleotide of group II and the antibody of group IV are patentably distinct for the following reasons:

The antibody of group IV includes, for example, IgG molecules which comprise 2 heavy and 2 light chains containing constant and variable regions, and including framework regions which act as a scaffold for the 6 complementarily determining regions (CDRs). Polypeptides, such as the antibody of group IV which are composed of amino acids, and polynucleotides, which are composed of nucleic acids, are structurally distinct molecules; any relationship between a polynucleotide and polypeptide is dependent upon the information provided by nucleic acid sequence open reading frame as it corresponds to the primary amino acid sequence of the encoded polypeptide. In the present claims, a polynucleotide of group II will not encode an antibody of group IV, and the antibody of group IV cannot be encoded by a polynucleotide of group II. Therefore, the antibody and polynucleotide are patentably distinct.

The antibody and polynucleotide inventions have a separate status in the art as shown by their different classifications. Furthermore, searching the inventions of group II and group IV would impose a serious search burden since a search of the polynucleotides of group II would not be used to determine the patentability of any antibody of group IV, and vice-versa.

The inventions of groups V-VII, IX, XI-XVIII, and XX are materially distinct methods. Group V is drawn to a method of detecting a targeting polynucleotide in a sample, group VI is drawn to a method for treating a disease comprising administering an antibody, group VII is drawn to a method of screening a compound for effectiveness as an agonist or antagonist, group IX is drawn to a method for treating a disease comprising administering an agonist, group XI is drawn to a method for treating a disease comprising administering an antagonist, group XII is drawn to a method of screening for a compound that binds a polypeptide of SEQ ID NO:1, group XIII is drawn to a method for screening for a compound that modulates the activity of a polypeptide of SEQ ID NO:1, group XIV is drawn to a method for screening for a compound for effectiveness in altering expression of a target polypeptide of SEQ ID NO:1, group SV is drawn to a method of screening for potential toxicity of a test compound, group SVI is drawn to a method to test for a condition or disease, group SVII is drawn to a method of detecting a polypeptide, group XVIII is drawn to a method of purifying a polypeptide, and group XX is drawn to a method of generating an expression profile of a sample.

These methods differ at least in objectives, method steps, reagents and/or dosages and/or schedules used, response variables, and criteria for success.

Inventions I and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polypeptide can be used in the materially different process of making antibodies.

Inventions X and XI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antagonist can be in the materially different process of antibody production.

Inventions I and XII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polypeptide

can be used in the materially different process of screening for a compound that modulates the activity of SEQ ID NO:1.

Inventions I and XIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polypeptide can be used in the materially different process of screening for a compound that specifically binds a polypeptide of SEQ ID NO:1.

Inventions IV and XVII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antibody can be used in the materially different process of affinity chromatography.

Inventions IV and XVIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different

process of using that product (MPEP § 806.05(h)). In the instant case the antibody can be used in the materially different process of affinity chromatography.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Note:

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sean E. Aeder, Ph.D. whose telephone number is 571-272-8787. The examiner can normally be reached on M-F: 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SEA

GARY B. NICKOL, PH.D.
PRIMARY EXAMINER